No. 2014-1035
(Serial No. 11/645,067)

United States Court of Appeals for the Federal Circuit

IN RE RONALD S. KARPF

Appeal from the United States Patent and Trademark Office,
Patent Trial and Appeal Board

OPENING BRIEF FOR APPELLANT RONALD S. KARPF

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January 21, 2014

CERTIFICATE OF INTEREST

Counsel for Appellant, Christian J. Hurt, certifies the following:

1. The full name of every party or amicus represented by me is: Ronald S. Karpf.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is: Electronic Compliance Promoter, Inc.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are: None

4. The names of all law firms and partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are: Nix Patterson & Roach, LLP; Christian J. Hurt; Derek Gilliland; Dickstein Shapiro LLP; Eric Oliver.

DATED: January 21, 2014.

Respectfully submitted,

_____
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STATEMENT OF RELATED CASES

There have been no other appeals in this proceeding from the Patent Trial and Appeal Board ("Board") or any other appellate court. Counsel for Appellant is not aware of any other cases pending in this or any other court that will directly affect or directly be affected by this Court's decision in this appeal.

JURISDICTIONAL STATEMENT

This is an appeal from a final decision of the Board. This Court has jurisdiction under 28 U.S.C. § 1295(a)(4)(A).

STATEMENT OF THE ISSUES

This appeal presents three issues: (1) whether substantial evidence supports the Board's findings that U.S. Patent No. 5,845,255 ("Mayaud") anticipates claims 9–18 and 23–25 of Application No. 11/645,067 (the "'067 Application"); (2) whether the Board violated the Appellant's due process rights under the Administrative Procedure Act ("APA"), 5 U.S.C. § 500 *et seq.*, by failing to designate its affirmance of the examiner's anticipation rejection as a new ground of rejection; and (3) whether the Board's decision contains adequate fact findings and analysis.

STATEMENT OF THE CASE

This appeal challenges the final decision of the Board, issued on March 18, 2013, J.A. 1–10, as well as the Board's decision that denied Mr. Karpf's Request for Rehearing, issued on July 26, 2013, J.A. 11–18.

STATEMENT OF THE FACTS

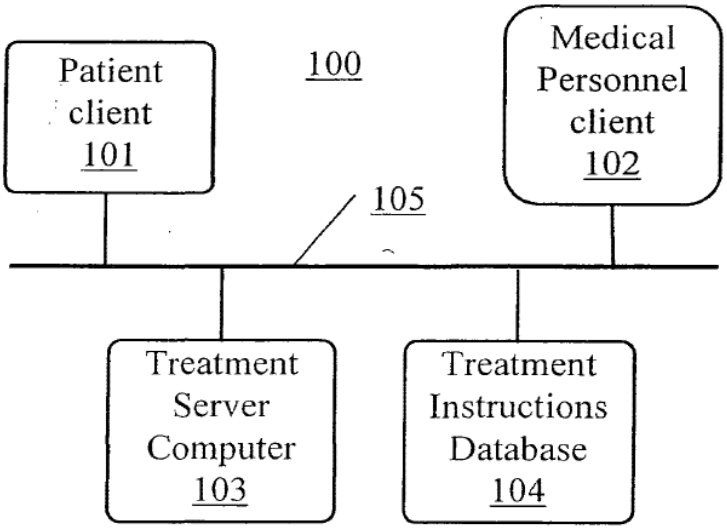
I. The '067 Application

The present invention relates to an electronic medical records database system. J.A. 23, [0004]. The inventors, Ronald S. Karpf and Arthur B. White, filed the '067 Application in 2006.[1] The '067 Application claims priority to a patent application filed in August, 1999.

The '067 Application discloses a system in which medical personnel and patients can each access a medical records database through different computer applications. A patient accesses the database through a patient program using the patient's username and password. J.A. 41, [0054]; J.A. 43, [0058–59]; J.A. 46, [0065]. A medical professional accesses the database through a medical personnel program using that professional's username and password. J.A. 51–52, [0079]. In the preferred embodiment, the database contains treatment instructions within the medical records, and the patient accesses the treatment instructions database (104)

[1] Mr. White passed away during the proceedings below. The real party in interest in the '067 Application is Electronic Compliance Promoter, Inc. For ease of reference, this Brief will refer to the Appellant as "Mr. Karpf."

through a patient client computer (101) and medical personnel access the database through a medical personnel client computer (102):



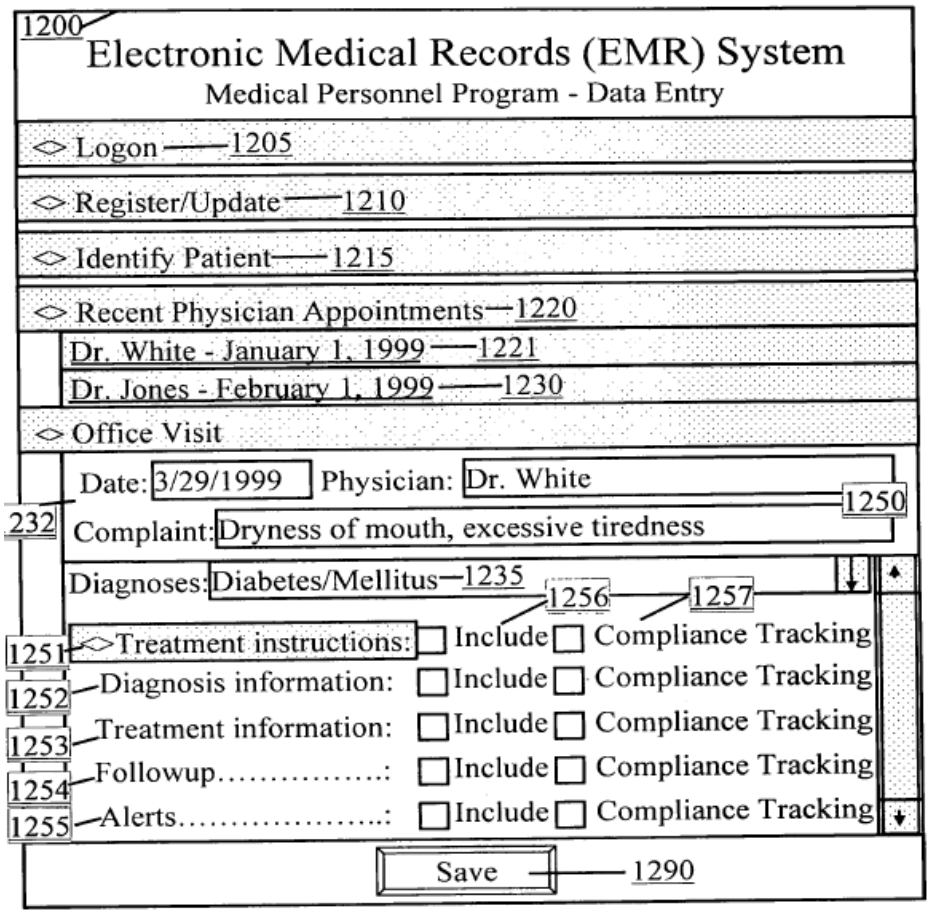
J.A. 120, Fig. 1.

The system is designed to facilitate the exchange of information between a patient and a doctor after a doctor's appointment. After a patient visits the doctor's office, a medical employee logs in to the medical personnel program and accesses the patient's medical record. To access the patient's medical record, in addition to being an authorized medical personnel user, the employee must enter the patient's username as well as the patient's "PIN," a unique identification number that "control[s] access to information" in that patient's medical record. J.A. 109–10, claim 9; *see also* J.A. 46–47, [0065–67]; J.A. 51–52, [0079]; J.A. 128, Fig. 11. The medical employee then enters information about the medical encounter for the patient, such as the reason for the doctor's visit and the patient's diagnosis. J.A. 55–56, [0083–84]; J.A. 129, Fig. 12. The medical employee also enters patient

compliance information, such as treatment instructions, and whether to track compliance or provide alerts. J.A. 56, [0084–85]; J.A. 129, Fig. 12.

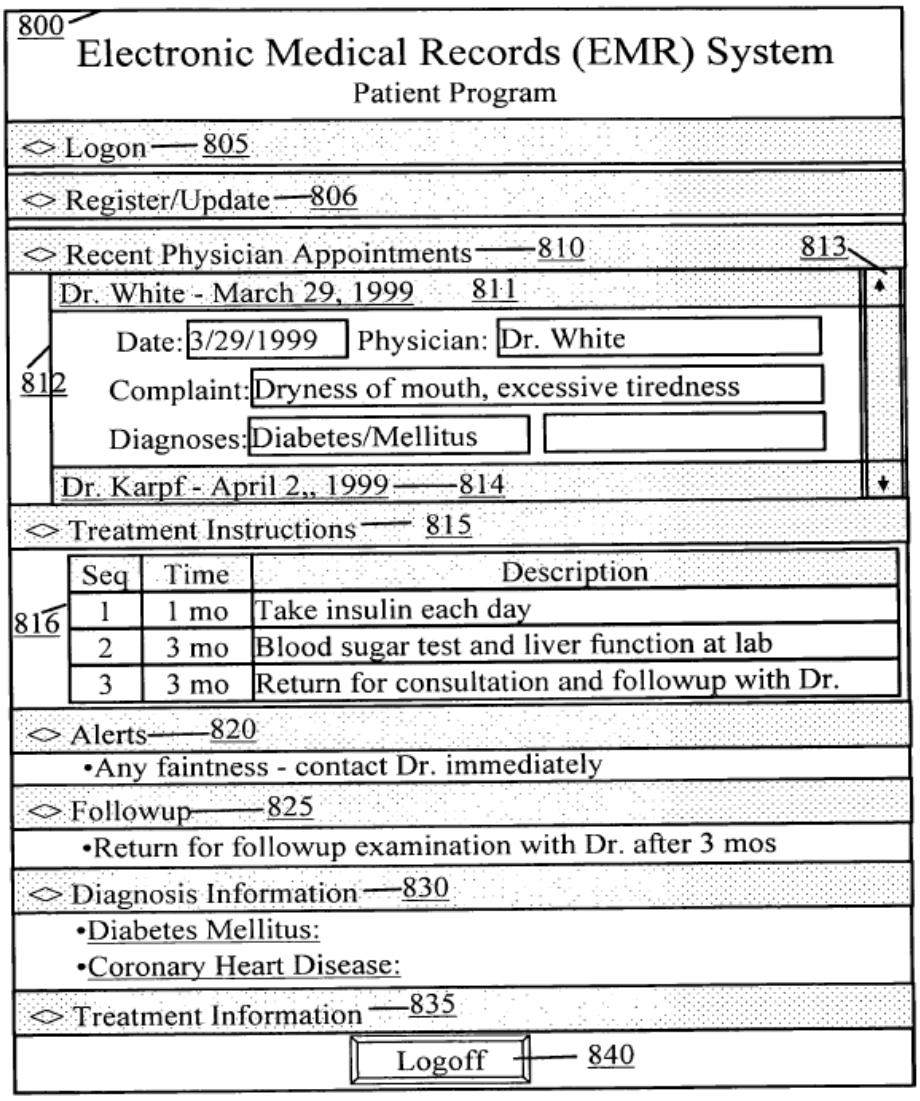
The patient accesses that medical information through a separate patient program. Using the patient's login and password (which is different than the patient's PIN), the patient program accesses the database system. J.A. 46, [0065]. The system then provides a list of recent appointments, from which the patient can select an appointment and view medical information. J.A. 48, [0070]; J.A. 124, Fig. 7.

The '067 Application provides a specific example to illustrate the sharing of post-appointment information between a patient and medical personnel. In the example, a patient has an appointment with Dr. White on March 29, 1999. J.A. 129, Fig. 12. At the visit, the patient complained of dryness of the mouth and excessive tiredness. *Id.* Dr. White then diagnosed the patient with diabetes/mellitus and provided specific treatment instructions, alerts, follow-ups, and information about the diagnosis. *Id.* After the appointment, a medical employee logged in to the medical personnel program and entered this information using the user interface depicted in Figure 12:



J.A. 129, Fig. 12.

After the medical employee enters this information via the medical personnel program, the system stores the patient-related information in the electronic medical records database. After the appointment, the patient can retrieve certain information by logging in to the patient program and double-clicking on the March 29, 1999 appointment with Dr. White. J.A. 48, [0070]; J.A. 124, Fig. 7. After clicking on that appointment, the patient is able to view the summary of that medical encounter, which resulted in a diabetes diagnosis, instructions to treat the diabetes, and information about the diagnosis:



J.A. 125, Fig. 8.

In addition to providing this information to the patient, the ’067 Application also provides a mechanism that allows medical personnel to monitor if a patient has complied with the treatment instructions. The system uses the patient’s access to particular treatment instructions as a proxy to determine whether the patient has complied with those instructions. Namely, the system monitors if the patient has accessed each treatment instruction linked to the medical encounter stored in the

database. J.A. 40–41, [0052]; J.A. 122, Fig. 4. If a patient has accessed a particular treatment instruction, the system concludes that the patient has complied with that instruction. *Id.* The system then calculates a measure of compliance by comparing the number of accessed treatment instructions with the number of total treatment instructions provided to the patient, as described in Figure 4:

400

Patient Access	Rule	Measure of Compliance
(401) No access	Accessed item = 0	Non Compliant
Partial access (402)	Accessed item < Total items	Partially compliant
Full Access (403)	Accessed item = Total items	Fully Compliant

J.A. 122, Fig. 4.

The medical compliance information is stored in the database, and the computer system utilizes that information in a number of ways. For example, a doctor can view a patient's compliance information and cause the system to send a reminder email. J.A. 59–61, [0091–93]; J.A. 132, Fig. 15; J.A. 133, Fig. 16. Conversely, medical personnel, using the medical personnel program, can configure the database system to automatically send reminders to the patient to comply with the treatment. *Id.*

The issues in this appeal center around the patient-focused limitations of the '067 Application claims: the patient program; the patient password; and the storing

or displaying of data related to the medical encounter, patient compliance, and medical condition. There are two sets of claims at issue in this appeal: method claims 9–18 and article of manufacture claims 23–25. Claim 9 recites a method of using an electronic medical records system:

> 9. A method of using an electronic medical records (EMR) system, the method comprising:
>
> a) forming an EMR database comprising:
>
> al) for at least *one patient registered to use the EMR system*, storing: patient identification data; *patient password*; and patient personal identification number (PIN);
>
> a2) for at least one medical practitioner registered to use the EMR system, storing: medical personnel identification data; and medical personnel password;
>
> a3) for at least one medical encounter between a patient and medical personnel, *storing medical encounter data relating to the at least one medical encounter, wherein the medical encounter data includes information related to the at least one reason for the medical encounter, and at least one diagnosis by medical personnel corresponding to the medical encounter*;
>
> b) *allowing access to the EMR database through a patient program, in which an authorized patient has access only to information related to the authorized patient*, wherein *the authorized patient* is assigned a patient PIN in the EMR database *for controlling access to information in the EMR database related to the patient*; and

> c) allowing access to the EMR database through a medical personnel data entry program, in which authorized medical personnel may access records related to a given patient only upon entry of input data corresponding to the patient PIN assigned to the given patient.

J.A. 109–10, claim 9 (emphases added). Claim 23 is an article of manufacture claim that likewise distinguishes between patient-access and medical personnel-access to the electronic medical records database and requires the storing of specific patient-related data:

> 23. An article of manufacture comprising at least one machine-readable storage medium having stored therein indicia of a plurality of machine-executable control program steps, the control program comprising the steps of:
>
> > a) storing patient data, including patient identification data, and *patient password*;
> >
> > b) *storing medical encounter data relating to at least one medical encounter between a medical personnel and a patient, wherein the medical encounter data includes at least one reason for the medical encounter, and at least one diagnosis by medical personnel corresponding to the medical encounter*; and
> >
> > c) *storing medical condition data relating to at least one medical condition that may be deemed by medical personnel to relate to a patient as a result of a medical encounter, wherein medical condition data includes general information about a given medical condition*.

J.A. 115–16, claim 23 (emphases added). The dependent claims at issue in this appeal further refine the storing and use of patient-related data contained in the

electronic medical records database. Claims 13 and 14 require "storing compliance information related to at least one diagnosis associated with a given medical encounter stored in the EMR database." J.A. 111–12, claims 13, 14. Claim 17 requires "selecting for display compliance information for at least one medical encounter for the given listed patient." J.A. 113, claim 17. Claim 24 requires "determining patient compliance . . . with the treatment information stored . . . for a given medical encounter." J.A. 116, claim 24. Lastly, claims 24 and 25 recite "issuing a notification" regarding the patient's compliance. J.A. 116, claims 24, 25.

II. The Mayaud Reference

The substantive issues on appeal relate to whether Mayaud discloses the patient-access limitations and the patient-related data limitations of the '067 Application claims. Mayaud is an issued patent, and it was not disputed before the Board that Mayaud is a prior art reference under § 102(e). The reference is entitled "Prescription Management System." J.A. 303. In particular, the reference "relates to a computer-implemented prescription management system to assist physicians in prescribing and reviewing drugs." J.A. 326, col. 1 ll. 15–18.

At a high level, Mayaud discloses a system of computers that physicians, during an appointment, can use to prescribe medications to a patient, manage that patient's prescriptions, and communicate with other physicians or a pharmacy.

J.A. 303, Abstract; J.A. 329, col. 7 l. 13–col. 8 l. 32. To use the system, a physician or another medical professional logs in and selects a patient whose prescriptions the medical professional seeks to manage. J.A. 306, Figure 2; J.A. 333–34, col. 16 l. 38–col. 17 l. 20. After selecting a patient, the medical professional can create a new prescription and review information associated with the medication, related medications, and the prescription history. J.A. 307–16, Figures 3–12.

One of the "critical" concerns in Mayaud is "issues of security, since the system requires access to personal records." J.A. 334, col. 17 l. 22–24. To that end, the system "provides data access controls such that the only accesses that can occur are those that have been authorized or preauthorized, at a point of care or elsewhere, in accordance with security profiles on the network established on behalf of data-proprietor entities such as patients, physicians or organizations." J.A. 334, col. 17 ll. 30–36. One of the "data access controls" that Mayaud discloses is "patient record access codes" (also referred to as "data access control cards") that a patient can furnish to medical professionals to grant access to that patient's records on a "need-to-know basis" by "physicians and other users." J.A. 330, col. 10 ll. 12–27; J.A. 348–49, col. 46 l. 32–col. 47 l. 46.

Mayaud also discloses the software that enables the prescription management system to read "data access rights" off of the patient's "data access

control card" such that an authorized medical professional can access that patient's medical record. J.A. 348–49, col. 46 l. 32–col. 47 l. 46. Mayaud refers to that software as "patient-directed data access control software." *Id.*

III. The Board's Original Decision

After the examiner rejected claims 9–18 and 23–25 as anticipated by Mayaud, Mr. Karpf appealed the examiner's rejections to the Board. Mr. Karpf specifically challenged the examiner's determinations that Mayaud discloses the patient-access limitations and the patient-related data limitations, including the limitations present in the dependent claims.

The Board upheld the examiner's anticipation rejections.[2] The Board only addressed the patient access and medical encounter limitations in the independent claims. It did not address the compliance information limitations in the dependent claims or the medical condition data-related limitations in independent claim 23. Focusing on claim 9, the Board relied exclusively on the following passage of Mayaud discussing "password protection" and "patient record access codes" to hold that Mayaud discloses the patient-access limitations of the '067 Application claims:

[2] The examiner also rejected the claims under 35 U.S.C. § 112 as indefinite and lacking written description. The Board reversed those rejections, J.A. 6, and that aspect of the Board's decision is not on appeal.

> Security may be provided by password protection operating hierarchically on one or more levels, to provide varying degrees of access according to the user's level of authorization, as desired. Additional password or numeric code control may protect sensitive system-accessed information, for example, patient records, or parts thereof, or physician-user data, including personal lists and prescribing profiles.
>
> Patient record access codes can, in selected instances, be patient provided, or granted by intelligent security control cards, having been furnished to the patient by a system administrator, or agent, prior to the physician encounter. Physician or other user access to a patient's record, or to sensitive details thereof, can thereby be restricted to a need-to-know basis. Access by third parties to physician-related data can be similarly protected.
>
> . . . .
>
> A still more preferred feature is to have user passwords which link each user with an individual profile or style sheet on the host computer facility representing the user's pattern of preferences so that the user-customization features of the system, which will be described more fully hereinafter, are readily available to the user independently of the particular interface device that happens to be employed for accessing the system.

J.A. 7–8; J.A. 330, col. 10 ll. 12–27, ll. 44–51. Regarding the medical-encounter data limitation in claim 9, the Board found that Mayaud disclosed this limitation because it disclosed "storing a patient history file and medical record, including diagnostic information to assist physicians or health care provider to make informed decisions regarding a patient." J.A. 8. In the alternative, the Board held that the medical encounter data elements were "non-functional descriptive

material" and thus were not "entitled to weight in the patentability analysis." J.A. 8–9 n.5.

The Board found, without a separate analysis, that Mayaud anticipated claim 23 for the same reasons it anticipated claim 9, even though claim 23 recites the "storing medical condition data" limitation that is absent from claim 9. J.A. 9. The Board also did not address Mr. Karpf's arguments regarding the "compliance information" limitations in the dependent claims. *See* J.A. 8–9.

IV. The Board's Decision on Rehearing

Mr. Karpf, proceeding pro se, requested rehearing. The Board denied his request. Regarding the patient-access limitations in claim 9, the Board again relied on the passage from column 10 of Mayaud reproduced above. J.A. 13–14. The Board also relied on a new passage from Mayaud that neither the Board nor the examiner relied upon during the proceedings. J.A. 15–16. Specifically, the Board found that Figure 16 and its accompanying text disclosed "a number of user devices . . . having data access control software and related data files installed therein for access to data by (1) patients, (2) care providers, and (3) organizations." J.A. 15 (citing J.A. 348–49, col. 45 ll. 18–25, col. 46 ll.41–49, col. 47 ll. 45–46). The Board further found that the system in Figure 16 disclosed services that include "patient-directed data access control software to allow a patient at any one of the user devices . . . to access the database system by way of 'Patient Record

Access Codes' (i.e., patient's data access control card)." *Id.* (citing J.A. 348–49, col. 46 ll. 32–49, col. 47 ll. 45–46). The Board also found that Mayaud discloses the medical-encounter limitations, and, regardless, those limitations and the patient compliance information limitations merely claim non-functional descriptive material that is not limiting. J.A. 16–17. Lastly, the Board, without analysis, upheld the examiner's rejections of claims 17, 24, and 25. J.A. 17. The Board did not address the "storing medical condition data" limitation in independent claim 23. Mr. Karpf timely appealed.

SUMMARY OF THE ARGUMENT

The Board erred in its anticipation decision. The Board first read into Mayaud features that simply are not there. Mayaud discloses a system exclusively for use by doctors and medical professionals and plainly fails to describe the patient-specific limitations claimed in the '067 Application. Rather than accept that reality, the Board stretched Mayaud—which discloses a "Prescription Management System"—to cover the patient-focused patient-access and medical-encounter-data limitations in the '067 Application claims. In its decision, the Board did not address the patient compliance and medical condition data limitations found in a number of claims.

The Board then dug in on rehearing. It pointed to a new portion of Mayaud to justify its finding that the reference discloses that a patient is intended to access

the Prescription Management System. It summarily dismissed Mr. Karpf's arguments regarding the patient compliance limitations and concluded that, in any event, they are not entitled to patentable weight. And it again failed to address the medical condition data limitations in three of the claims.

The law governing a Board finding of anticipation is strict. "To anticipate a patent claim, a prior art reference must describe 'each and every claim limitation and enable one of skill in the art to practice an embodiment of the claimed invention without undue experimentation.'" *ClearValue, Inc. v. Pearl River Polymers, Inc.*, 668 F.3d 1340, 1343 (Fed. Cir. 2012) (quoting *Am. Calcar, Inc. v. Am. Honda Motor Corp.*, 651 F.3d 1318, 1341 (Fed. Cir. 2011)). As part of that analysis, the U.S. Patent & Trademark Office (PTO) "must consider all claim limitations," *In re Lowry*, 32 F.3d 1579, 1582 (Fed. Cir. 1994), and the Board has the limited role to "review the examiner's decisions during prosecution," *In re Stepan Co.*, 660 F.3d 1341, 1344 (Fed. Cir. 2011).

The Board ran afoul of that law when, in its shifting opinions, it excised some limitations from the claims, ignored other limitations, and recast Mayaud's disclosure to cover a patient-focused medical computer system. But regardless of how the Board attempted to mold the facts of this case to reach its anticipation decision, the plain import of the claims and Mayaud is inescapable: the '067 Application claims a comprehensive medical records database system separately

accessed by patients and medical personnel that stores and tracks patient-specific data, and Mayaud discloses a prescription management system accessed by medical professionals that displays limited prescription information about a patient. As a consequence, there are four sets of patient-specific limitations that Mayaud fails to disclose: patient access to the electronic medical records system; the storing of medical encounter data; the storing and displaying of compliance information; and the storing of medical condition data. Each limitation affects different groups of claims on appeal, as the following table shows:

Claim Limitations	**Impacted Claims**							
	9–12	13–14	15	16	17	18	23	24–25
Patient Access	X	X	X	X	X	X	X	X
Medical Encounter Data	X	X	X	X	X	X	X	X
Compliance Information		X	X		X			X
Medical Condition Data							X	X

Accordingly, Mr. Karpf respectfully requests that the Court reverse the Board's decision holding anticipated claims 9–18 and 23–25.

ARGUMENT

I. Standard of Review

The Court reviews the Board's factual findings for substantial evidence and its legal conclusions *de novo*. *In re Gartside*, 203 F.3d 1305, 1316 (Fed. Cir. 2002). Anticipation is a question of fact reviewed for substantial evidence. *In re*

Gleave, 560 F.3d 1331, 1334–35 (Fed. Cir. 2009). Substantial evidence is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Consol. Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938). Whether the Board relied on a new ground of rejection is a legal question that the Court reviews *de novo*. *Stepan*, 660 F.3d at 1343.

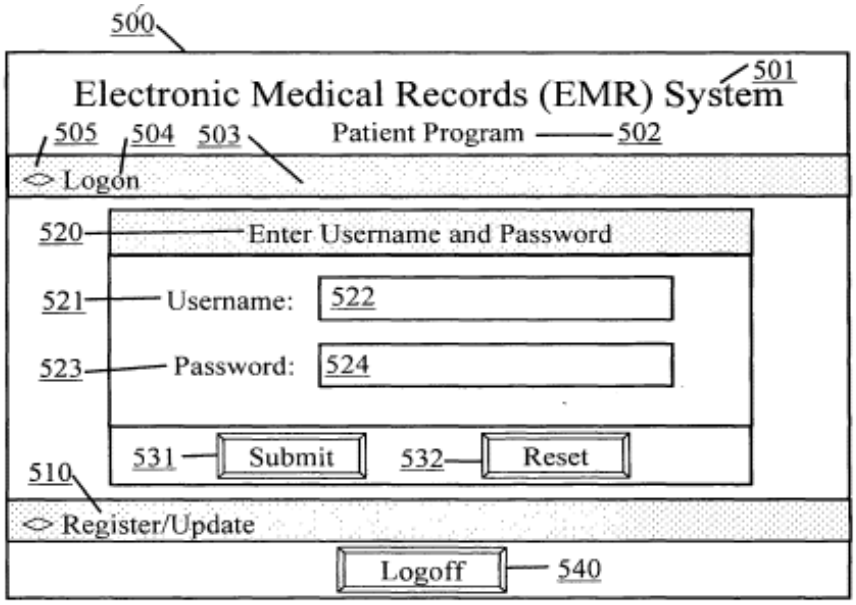
II. Mayaud Fails to Disclose Patient Access to a Medical Record Database

Mayaud does not disclose the patient-access limitations present in every claim of the '067 Application on review. Claim 9, for example, requires a "patient registered to use the EMR system" that accesses the system through a "patient program" using a "patient password." Claim 23 requires a "patient password." Mayaud fails to disclose any of those claim limitations, and the Court can reverse the Board's decision in its entirety on that basis alone.

A. The '067 Application Distinguishes Between Access By a Patient and Access By a Medical Professional

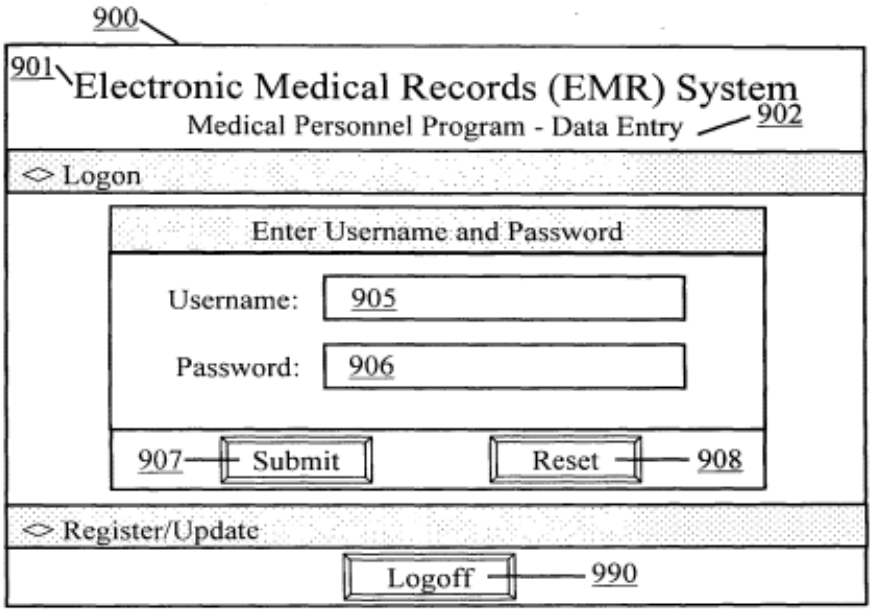
The '067 Application distinguishes between patient access to the electronic medical records database system and medical personnel access to the system. On the patient side, the Application claims a "patient program," which is a program that allows a registered patient to, among other things, review treatment instructions or receive reminders to comply with medical treatment. J.A. 41, [0054]. The patient accesses the patient program by entering a username and a

patient password. J.A. 43, [0058–59]; J.A. 46, [0065]. Figure 5 of the '067 Application depicts an exemplary user interface of the patient program:



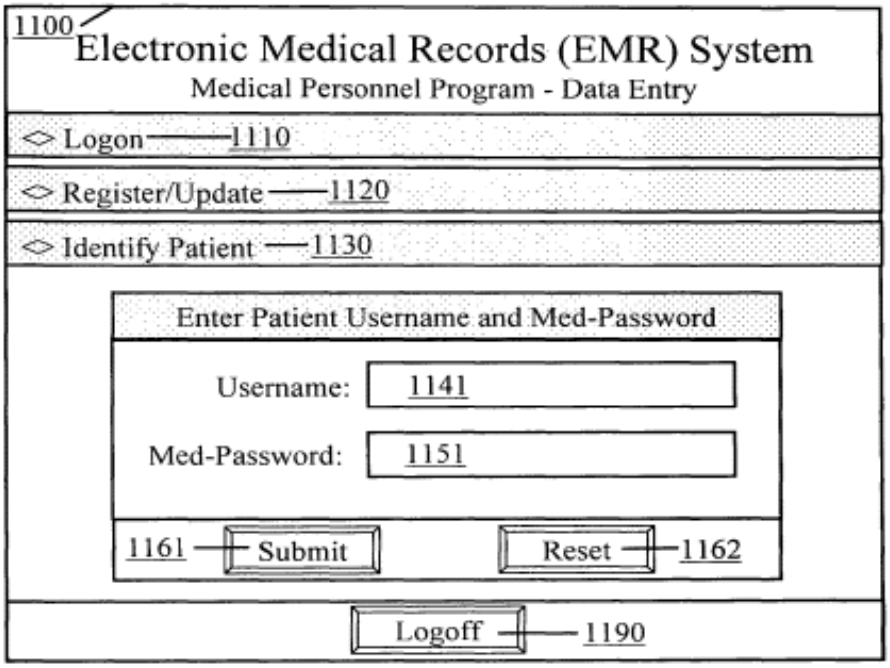
J.A. 122, Fig. 5.

The '067 Application provides a different interface for the "medical practitioner registered to use the EMR system." J.A. 47, [067]; J.A. 109–10, claim 9. Using a separate "a medical personnel data entry program," the medical practitioner gains access to the database by entering a username and a "medical personnel password." J.A. 51–52, [0079]; J.A. 109–20, claim 9. Figure 9 of the '067 Application depicts an exemplary user interface for the medical personnel program:



J.A. 126, Fig. 9.

Once the medical employee has logged in, the electronic medical records system prompts the employee to enter the patient username and "Med-Password" for that patient in order to access that patient's medical records. J.A. 51–52, [0079]. The user interface for this portion of the medical personnel program is depicted in Figure 11:



J.A. 128, Fig. 11.

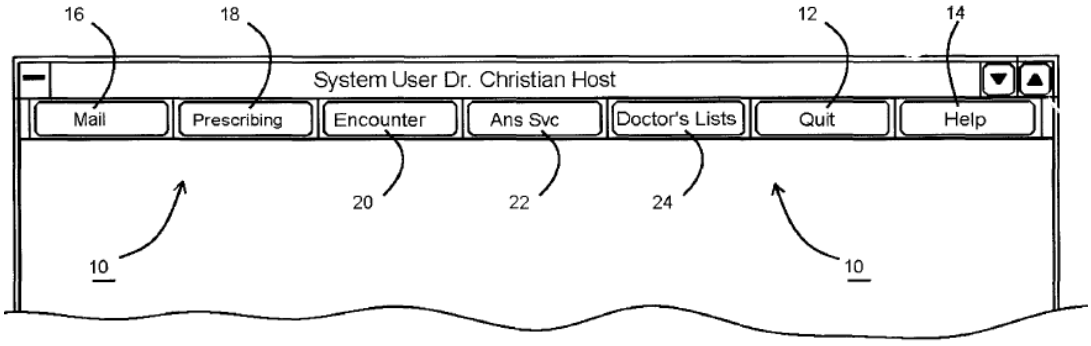
The "Med-Password" is another name for the claimed "patient PIN" that is assigned to that patient. J.A. 109–10, claim 9. It is not the separate "patient password" that the patient uses to access the electronic medical records database system.

The "patient PIN" and the "patient password" recited in the claims are thus two distinct elements with different functions. The "patient password" is "used by the patient to access their treatment instructions from the exemplary patient program." J.A. 46, [0065]. The patient does not use the PIN to access the medical records database. *Id.* Instead, an authorized medical employee uses a patient's PIN to access that patient's medical information through the "exemplary medical personnel program but not the exemplary patient program." *Id.* The patient

password is what provides the patient with "access to the EMR database through a patient program"; the "PIN" is used to "control[] access to information in the EMR database related to the patient." J.A. 109–10, claim 9.

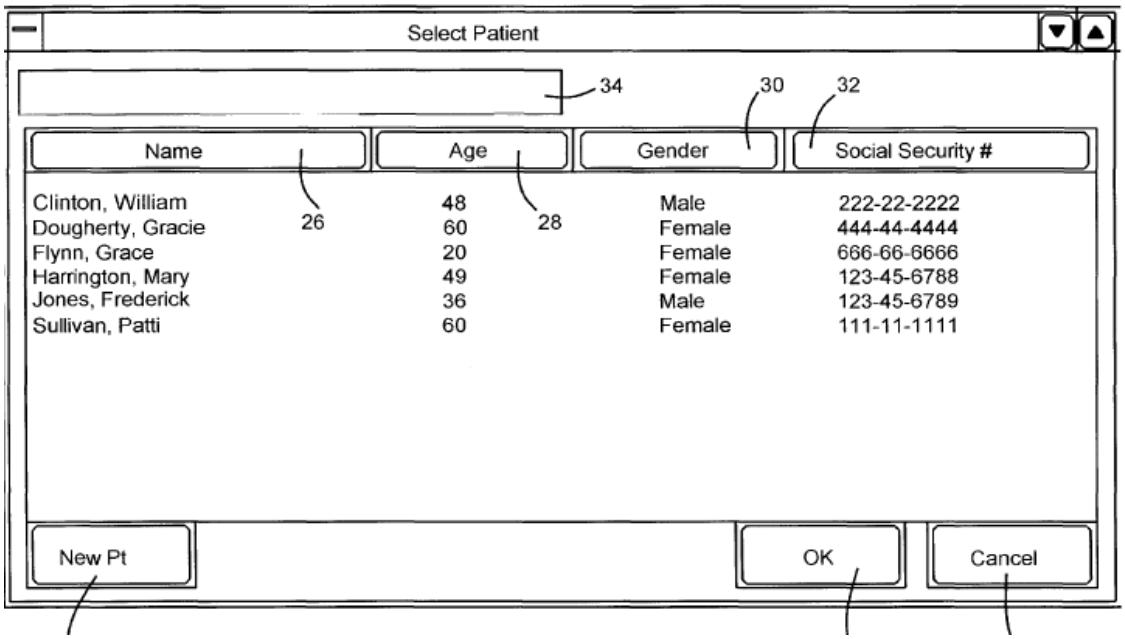
B. Mayaud Only Discloses Access to a Prescription System By a Medical Professional

Mayaud discloses a system that only medical professionals can access. Mayaud describes a computer with an application that allows physicians or other authorized medical professionals to prescribe medication to specific patients. J.A. 326, col.1 ll. 12–18. Mayaud discloses that the "user" is a medical professional, such as Dr. Host in Figure 1:



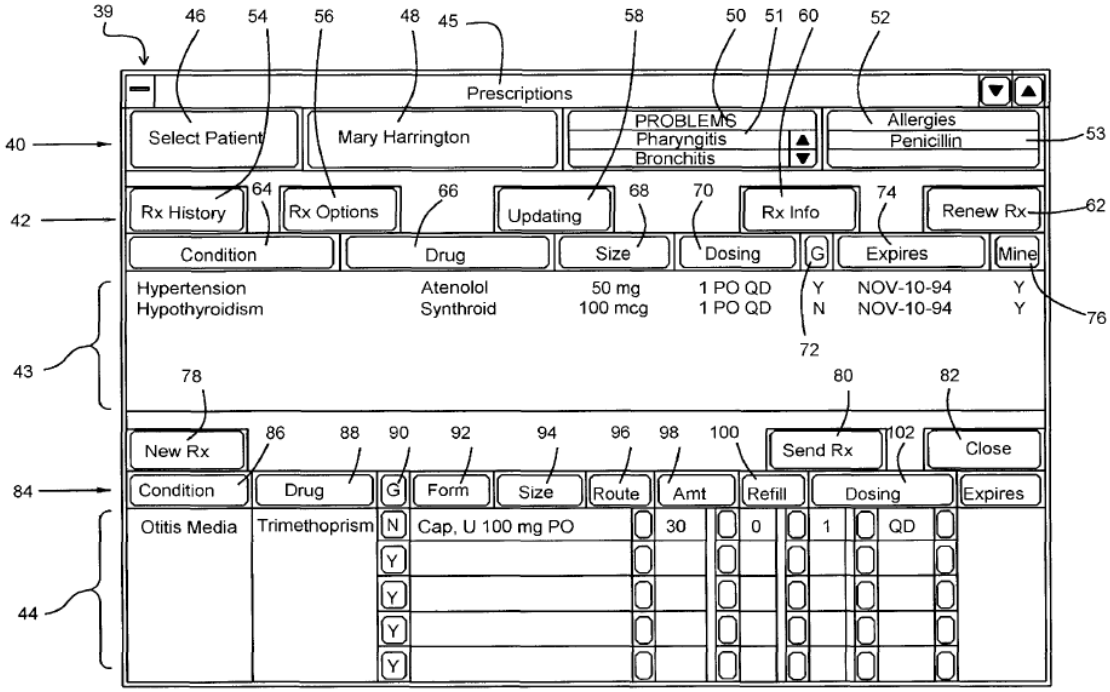
J.A. 305, Figure 1.

Once logged in, the user selects a patient from a list of patients to manage the prescriptions for that patient. Mayaud discloses the following interface, in which the medical professional selects a patient, such as "Clinton, William", from a list of patients tracked in the prescription management system:



J.A. 306, Figure 2.

After selecting a patient, the user can manage the patient's prescriptions. The interface that allows that management is depicted in Figure 3:



J.A. 307, Figure 3.

The graphical interfaces thus show that the "user" in Mayaud is always a medical professional, generally a physician. There is no disclosure of a patient program used by a registered patient that accesses the database with a patient password. The text of the reference likewise refers to medical professionals as the "users" of the system. *E.g.*, J.A. 303, Abstract ("A . . . system for physician use . . . ."); J.A. 328, col. 5 ll. 25–32 ("prescriber-users"); J.A. 329, col. 8 ll. 24–28 ("physician-user"); J.A. 330, col. 10 ll. 15–19 (same); J.A. 331, col. 12 ll. 37–41 ("physician user"); J.A. 331, col. 12 ll. 49–54 ("user physician"); J.A. 332, col. 13 ll.25–30 ("physician user"); J.A. 332, col. 14 ll. 10–31 ("physician-user"); J.A. 332–33, col. 14 l. 66–col. 15 l. 6 (same); J.A. 333, col. 16 ll. 62–66 ("user physician"); J.A. 334, col. 17 ll. 40–44 ("physician-user"); J.A. 334, col. 17 l.66–col. 18 l.2 ("[A]ssociated with every patient record is a timed and dated log of every physician user, organization or health care professional accessing that record."); J.A. 334, col. 18 l. 26–29 ("physician user"); J.A. 335, col. 19 ll. 63–67 ("physician-user"); J.A. 335, col. 20 ll. 5–32 ("physician user"); J.A. 336, col. 22 ll. 6–8 (same); J.A. 337, col. 23 ll. 19–22 (same); J.A. 337, col. 23 ll. 61–67 (same); J.A. 337, col. 24 ll. 22–24 (same); J.A. 338, col. 25 ll. 5–8 (same); J.A. 338, col. 25 ll.36–39 ("physician-user"); J.A. 338, col. 26 ll. 57–60 (same); J.A. 339, col. 27 ll. 18–27 ("physician user"); J.A. 341, col. 31 ll. 36–39 ("physician-user"); J.A. 342, col. 33 ll. 9–13 ("physician user"); J.A. 342, col. 34 ll. 34–39

("physician-user"); J.A. 343, col. 35 ll. 23–30 ("user-physician"); J.A. 345, col. 40 ll. 45–47 ("physician-user"); J.A. 346, col. 42 ll.7–9 ("user-physician"). Indeed, Mayaud claims "[a] computer-implemented prescription system . . . for use by a prescriber." J.A. 352–53, claim 1. Mayaud simply does not disclose a patient as a registered user, a patient program, or a patient password.

Similar to the use of the "patient PIN" in '067 Application, Mayaud discloses a security feature that controls which medical professionals can access the prescription records for a particular patient. The reference describes that patients may have "patient record access codes" (also referred to as "data access control cards") that they can furnish to grant access on a "need-to-know basis" to "physicians and other users." J.A. 330, col. 10 ll. 12–27; J.A. 348–49, col. 46 l. 32–col. 47 l. 46. The authorized medical professionals use those codes / cards to access a patient's records through the prescription management program. The treated patient in Mayaud is "a patient who has authorized the user physician to treat him." J.A. 333, col. 16 ll. 64–65. The "patient record access codes" are the mechanisms that provide that authority. They are not a patient password that grants a registered patient access to a medical records database through a patient computer program.

C. The Board's Original Findings Lack Substantial Evidence

Despite Mayaud's one-sided disclosure, the Board found that the reference discloses the patient-access limitations of the '067 Application claims. This was error.

In its decision, the Board found that "the patient can also be granted access" to an electronic medical record because Mayaud discloses that a patient may have a "patient access code" that restricts access to the prescription management system:

> Patient record access codes can, in selected instances, be patient provided, or granted by intelligent security control cards, having been furnished to the patient by a system administrator, or agent, prior to the physician encounter. Physician or other user access to a patient's record, or to sensitive details thereof, can thereby be restricted to a need-to-know basis. Access by third parties to physician-related data can be similarly protected.

J.A. 7 (quoting J.A. 330, col. 10 ll. 20–27) (emphase removed). The Board then found that "once a patient is authorized access to Mayaud's prescription creation system, 'patient passwords' or other forms of password protection operating hierarchically at one or more levels are also provided, with varying degrees of access according to the user's level of authorization, as desired." J.A. 8.

Those findings lack substantial evidence. The "users" in Mayaud are physicians and other medical professionals, not patients. In addition to the above references to "physician users," Mayaud distinguishes the medical professional

"users" from "their patients." J.A. 329, col. 7 ll. 13–20. The reference discloses that the prescription management system is for use "by physicians and other prescribers . . . and the invention can bring substantial benefits to such users and their patients." *Id.* Consistent with that disclosure, Mayaud only discloses that medical professionals access the system and manage the prescription of medicine to patients. It would be an odd result indeed if a patient could access a prescription management system and prescribe his own medication. It would also be against the law. *See e.g.*, 21 U.S.C. § 829(a) ("Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance . . . which is a prescription drug . . . may be dispensed without the written prescription of a practitioner . . ."). A person of ordinary skill simply would not read Mayaud the way the Board did.

The security in Mayaud thus must be understood in the medical personnel-access context. Mayaud explains that "[s]ecurity may be provided by password protection . . . to provide varying degrees of access according to the user's level of authorization." J.A. 330, col. 10 ll. 12–15. Again, the "users" in Mayaud are medical professionals, not patients. As a result, the "password protection" in Mayaud, if anything, relates to the "medical personnel password" recited in the '067 Application's claims, not the separately claimed "patient password."

Similarly, the "patient record access codes" in Mayaud are codes that limit a medical professional's access to a particular patient's records. They are not a separate "patient password" that provides a patient with access to the prescription management system. Nothing in Mayaud teaches patient access. Instead, Mayaud teaches that these "patient record access codes" are used to restrict "[p]hyscian or other user access to a patient's record . . . to a need-to-know basis." J.A. 330, col. 10 ll. 24–26. They are akin to the claimed "patient PIN" in the '067 Application that "control[s] access to information" in a database—they limit which medical professionals can access a patient's records; they do not affirmatively provide a patient with access to the system. J.A. 109–10, claim 9.

The Board failed to grapple with that distinction in Mayaud. The Board instead relied on a logical rationale for why "patient record access codes" inherently provide a patient with access to the prescription management system. It reasoned that the use of patient control codes to grant an authorized physician access to a patient's record "necessarily requires" that the patient have access to that record. J.A. 14–15. That logic is simply incorrect.

It does not necessarily follow that control over who can access a record requires the underlying ability to access that record. Control and access are distinct concepts, as reflected in the '067 Application. The claims recite that a patient "access[es] the EMR database through a patient program." J.A. 109–10,

claim 9. The patient uses a "patient password" to access the database. J.A. 43, [0058–59]; J.A. 46, [0065]. The patient does not use a PIN to access that database. J.A. 46, [0065]. Instead, as delineated in the claims, the purpose of the patient PIN is "controlling access to information in the EMR database related to the patient" for medical personnel. J.A. 109–10, claim 9. Medical personnel access the patient's data using a separate "medical personnel program," and the personnel "may access records related to a given patient only upon entry of input data corresponding to the patient PIN assigned to the given patient." *Id.*

A simple example further illustrates the distinction between access and control. A person may have a key to a locker located in a gym. But if she is not a member of the gym, she does not have access to the locker. Because she lacks access to the gym, she lacks access to the locker. She can, however, authorize a gym member to access the locker by giving the key to the member.

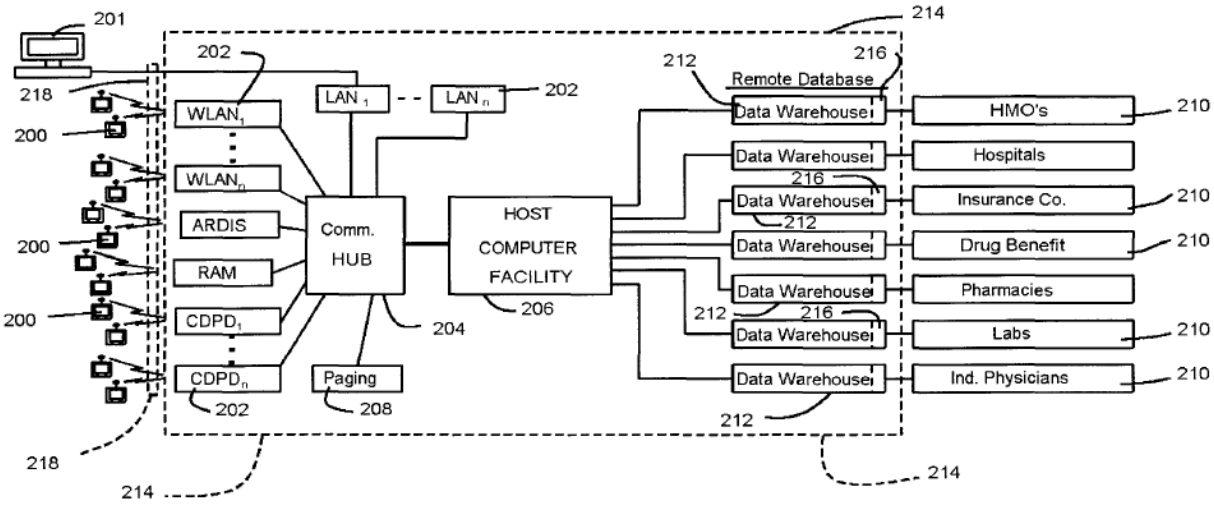
Like the holder of the gym locker key, the patients in Mayaud only hold codes that allow a medical professional to access the patient's records. The patients cannot access the database system that holds the records. They do not belong to the gym—only the medical professionals do. The user interfaces depicted in Mayaud are for use by medical professionals, and the reference only refers to physicians, prescribers, and other medical professionals as the system's users. *See e.g.*, J.A. 351, col. 52 ll. 43–47 ("[A]lthough the invention has been

described in its preferred embodiments with reference to a physician user it will be apparent that other medical professionals, especially those having prescribing authority, can benefit from applications of it."). They are the ones with the passwords. Just because a patient can control which medical professionals can access a particular record does not necessarily mean that the patient has access to the electronic record. Nowhere in Mayaud is the disclosure that patients can access the prescription management system with a "patient password," as required by the claims of the '067 Application. Because the Board erred in finding that the "patient record access codes" disclosed in Mayaud meet the patient-access limitations in claims 9–18 and 23–25, the Board's decision holding the claims anticipated should be reversed.

D. The Board's New Findings on Rehearing Also Lack Substantial Evidence

The Board's new findings on rehearing also lack substantial evidence. On rehearing, the Board found that Figure 16 of Mayaud discloses the patient-access limitations of the '067 Application claims. That finding lacks substantial evidence.

Figure 16 of Mayaud relates to the hardware components of the prescription management system. Reproduced below, the figure depicts the prescription management system in which users access the system via a user device (200):



J.A. 320, Figure 16.

As recounted above, Mayaud repeatedly explains that the users of the system are medical professionals, generally physicians. *E.g.*, J.A. 351, col. 52 ll. 43–47. The Board on rehearing, however, concluded that the users in Figure 16 could include patients. That finding, aside from being brand new, lacks supporting evidence in the reference.

The Board's finding on rehearing suffers from the same flaw as the Board's original decision: control over who can access a record is not the same as the ability to access that record. Mayaud discloses that a patient, via a "patient record access code" (also referred to as a patient's "data access control card"), can control which medical personnel or groups of personnel have access to that patient's records. J.A. 330, col. 10 ll. 13–27; J.A. 348, col. 46 ll. 33–49. Mayaud does not disclose that the patient can use the codes or control card as a password to login and access the prescription management system.

The Board based its contrary finding by misreading the "patient-directed data access control software" with "patient interface components" disclosed in the following text from Mayaud regarding Figure 16:

> Host computer facility 206 provides intelligent network services to user devices 200 and 201 and may support ancillary services, especially for example, as described hereinbefore, patient-directed data access control software. Prescriber-directed data access control software or organization-directed data access control software could also run in an application separated from the prescription management system, but is preferably integrated therewith as a component of a user initialization routine.
>
> Conveniently, patient interface components of the patient-directed data access control software are run at separate stations from the point-of-care locations used by prescribers and are located, for example, in administrative or reception areas of health care facilities or managed care organizations. Here, data access rights may be read off a patient's data access control card, and such cards may be issued, under control of software supplied by, and in communication with host computer facility 206.
> . . .
>
> Important functions maintained by the host computer facility 206 are information locator databases and advanced directory and routing services, including the following: . . . vi) access control software and related data files for patients, care providers and organizations.

J.A. 348–49, col. 46 l. 32–col. 47 l. 46. These passages, however, do not disclose that a registered patient can access the prescription management system through a patient program using a patient password. They disclose that a patient's data

access control card, when read by patient-directed data control software, can grant authorized medical professionals (the "users") access to that patient's record. The "patient-directed data access control software" is the computer software that enables a computer to read the "data access rights" off of the patient's "data access control card" so the system can provide authorized medical professionals with access to that patient's record. J.A. 348, col. 46 ll. 32–49. "Patient-directed data access" means that the patient directs which medical professionals can access the patient's record. This direction occurs by reading the data access control card or patient access codes using the patient interface components of the data access control software running on computers located in the reception area, waiting room, or point of care. J.A. 334, col. 17 ll. 30–36 ("[T]he system . . . provides data access controls such that the only accesses that can occur are those that have been authorized or preauthorized, at a point of care or elsewhere . . . ."); J.A. 348, col. 46 ll. 32–49 ("[P]atient interface components of the patient-directed data access control software are run at separate stations from the point-of-care locations used by prescribers and are located, for example, in administrative or reception areas of health care facilities or managed care organizations."). After the system reads that information, an authorized medical professional can access the patient's record in the prescription management system. The patient-directed data access control

software does not provide a separate patient program that allows a registered patient to access a medical records system using a patient password.

E. At a Minimum, the Board Entered a New Ground of Rejection When It Relied on New Passages from Mayaud

At a minimum, the Board entered a new ground of rejection when it relied on new passages from Mayaud to uphold the examiner's rejection. The Board has the "limited role to 'review the examiner's decisions during prosecution.'" *Rambus, Inc. v. Rea*, 731 F.3d 1248, 1255 (Fed. Cir. 2013) (quoting *Stepan*, 660 F.3d at 1344). Accordingly, the PTO's rules "provide that when the Board relies upon a new ground of rejection not relied upon by the examiner, the applicant is entitled to reopen prosecution or to request a rehearing." *In re Leithem*, 661 F.3d 1315, 1319 (Fed. Cir. 2011) (citing 37 C.F.R. § 41.50(b)). Those rules ensure that the PTO "fulfill[s] its notice obligation to the applicant during prosecution" under the APA, which requires the PTO to "provide prior notice to the applicant of 'all matters of fact and law asserted' prior to an appeal hearing before the Board." *Stepan*, 660 F.3d at 1345 (quoting 5 U.S.C. § 554(b)(3)). Conversely, failure to follow the Board's new ground of rejection procedure is a violation of an applicant's due process rights and requires the Court to vacate the Board's decision. *In re Biedermann*, 733 F.3d 329, 337 (Fed. Cir. 2013).

To determine if the Board has entered a new ground of rejection, the "ultimate criterion" is whether the applicant has "had fair opportunity to react to the thrust of the rejection." *Leithem*, 661 F.3d at 1319. While the Board does not need to recite the Examiner's rejection word-for-word, it cannot rely on "new facts and rationales not previously raised to the applicant by the examiner," even if the Board's decision rests on the "same statutory basis and same prior art references" as the examiner's. *Id.*

Here, the Board relied on new facts and rationales to support the examiner's anticipation rejection. On rehearing, the Board upheld the examiner's anticipation rejection by relying on a portion of Mayaud that was never raised during prosecution of the '067 Application. Namely, the Board held that the "patient-directed data access control software" and the "patient interface components" of that software disclosed in Figure 16 described the patient-access limitations of the '067 Application. J.A. 15. The examiner never relied on those portions of Mayaud when he rejected the claims, and those aspects of Mayaud were never at issue during prosecution. *See, e.g.*, J.A. 187, 192–93.

The Board's entry of a new ground of rejection was not harmless. Mayaud is a lengthy reference—21 Figures and 58 columns—and, during prosecution, Mr. Karpf and the examiner honed in on the disclosure of password protection and hierarchical security in columns 9 and 10, among other portions of Mayaud. *See,*

e.g., J.A. 187, 192–93. At no point did the examiner rely on the disclosure related to Figure 16. Had the examiner raised that portion of Mayaud, Mr. Karpf could have responded to traverse the rejection. He also could have amended the claims to overcome the rejection. He lacked the opportunity to do either. Thus, while the Board's decision lacks substantial evidence and should be reversed, at a minimum, the Court should vacate the Board's decision and remand this matter to the PTO to allow Mr. Karpf to respond to the Board's new rejection.

III. The Board Erred in Finding That Mayaud Discloses the Patient-Related Data Limitations

The Board also erred in finding that Mayaud discloses the storing and display of patient-related data claimed in the '067 Application. The Board's error was procedural and substantive. Procedurally, the Board erred by disregarding the "medical encounter data" (original decision) and the "patient compliance information" (on rehearing) limitations because they were merely descriptive material and thus lacked patentable weight. The Board also erred by failing to provide adequate findings and reasoning regarding the "patient compliance information" and "medical condition data" limitations. The Board did not address either limitation in its original decision. On rehearing, the Board only summarily mentioned some of the claims that contain the "patient compliance information" limitation, but did not provide any substantive analysis. At no point did the Board

address the "medical condition data" limitation. These procedural errors are grounds to vacate the Board's decision.

The Board also erred in substance. As discussed below, Mayaud does not disclose the patient-related data limitations.

A. The Data Elements Limit the Claims

The patient-related data elements limit the claims. It is axiomatic that the PTO "must consider all claim limitations when determining the patentability of an invention over the prior art" and "may not disregard claim limitations" on the basis that those limitation may be "comprised of printed matter." *Lowry*, 32 F.3d at 1582. The Board failed to follow that precedent. Instead, it concluded that the limitations related to the "storing" of "medical encounter data" and "compliance information" were "non-functional descriptive material," *i.e.*, printed matter, and thus "not entitled to weight in the patentability analysis." J.A. 8–9 (citing *Lowry*, 32 F.3d at 1583); J.A. 17 (same).

The printed matter doctrine does not apply here. Under the doctrine, limitations that are "useful and intelligible only to the human mind" are generally not entitled to patentable weight. *Lowry*, 32 F.3d at 1583 (quoting *In re Bernhart*, 417 F.2d 1395, 1399 (CCPA 1969)). However, the alleged printed matter is limiting if there is a "functional relationship" between the matter and its substrate. *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1064 (Fed. Cir. 2010). Because

the printed matter doctrine only applies to "printed matter," the doctrine has "no factual relevance where 'the invention as defined by the claims *requires* that the information be processed not by the mind but by a machine, the computer.'" *Lowry*, 32 F.3d at 1583 (quoting *In re Bernhart*, 417 F.2d 1395, 1399 (CCPA 1969)). This Court reviews *de novo* a determination that a claim limitation is not entitled to patentable weight. *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1064 (Fed. Cir. 2010).

Here, it is beyond dispute that the claims require "storing" the "medical encounter data," "medical condition data," and "compliance information" in a computer database. *See* J.A. 34, [0041] (describing the "MedEncounter" table and "MeasCompliance" entry in the database); J.A. 35–36, [0043–44] (describing the "Diagnosis" and "Diagnoses" database tables); J.A. 37–38, [0048] (describing the "Compliance" database table); J.A. 39–40, [0051] (describing the "PatCompliance" database table); J.A. 121, Fig. 3 (depicting database records). The data only has significance in the computer database system. It is not printed matter. It is not useful and intelligible only in the human mind. Because the claimed computer data is "not accessible other than through sophisticated software systems," the printed matter doctrine "ha[s] no factual relevance here," *Lowry*, 32 F.3d at 1583, and the Board erred in its contrary conclusion.

Moreover, the limitations that require "storing" of "medical encounter data," "medical condition data," and "compliance information" are not analogous to printed matter. There is a functional relationship between the data and the computer database system. The stored data exists in memory as a collection of bits that contain information read by a computer. That digital information enables the functionality of the electronic medical records database system. For example, the computer system monitors the patient-related information stored in the database to track a patient's compliance with treatment instructions and then "automatically generate[s] a reminder message if the patient is non-compliant." J.A. 39–40, [0051]; *see also* J.A. 60, [0092] ("All patients that are not fully up-to-date in reviewing the treatment information are automatically sent reminders."); J.A. 61, [0093] (explaining that Fig. 16 is an example of "an Email reminder that is sent automatically by the treatment information database program to a patient who is not fully compliant with the post-examination treatment instructions as measured by the 'Measure of Compliance' 400"); J.A. 133, Fig. 16. The printed matter doctrine simply does not apply.

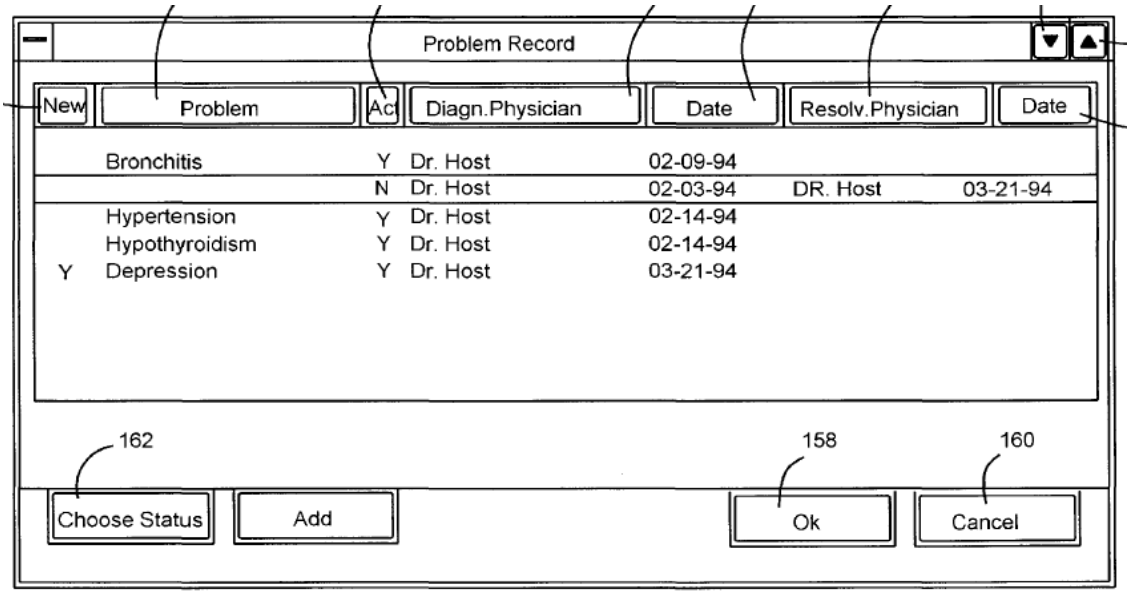
The patient-related data elements are claim limitations. The Board erred when it disregarded them in its anticipation analysis.

B. Mayaud Fails to Disclose Storing Medical Encounter Data

Mayaud does not disclose the storing of "medical encounter data." The '067 Application claims require that the stored "medical encounter data" contain at least two pieces of information "relating to the . . . medical encounter": (1) at least one reason for the medical encounter; and (2) at least one diagnosis by medical personnel corresponding to the medical encounter. *E.g.*, J.A. 109–10, claim 9. Mayaud fails to disclose storing both the diagnosis *and* the reason for a particular medical encounter. Because each claim on review contains the "medical encounter data" limitation, the Court can reverse the Board's decision in its entirety on this basis alone.

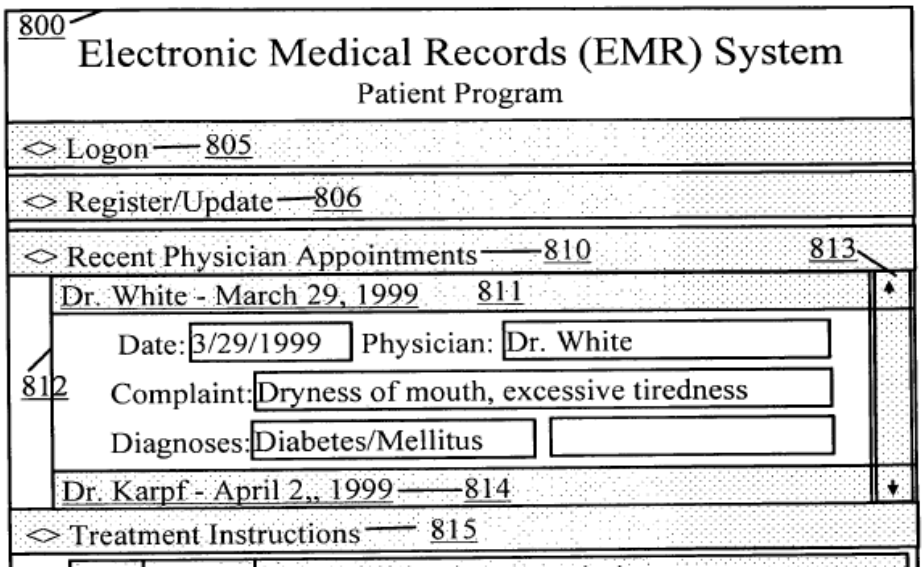
The Board found that Mayaud discloses this limitation because the reference teaches "storing a patient history file and medical record, including diagnostic information to assist physicians or health care professionals to make informed decisions regarding the patient." J.A. 8; J.A. 16. But that finding is not substantial evidence that Mayaud meets the storing medical encounter data limitation. The limitation requires the system to store *both* the "reason" and the subsequent "diagnosis" for a given medical encounter, and the Board's finding says nothing about whether the system disclosed in Mayaud stores the impetus or "reason" that the patient sought the "medical encounter" in the first place. Indeed, the "patient file history and medical record" depicted in Mayaud does not contain the reason

for a medical encounter along with a diagnosis—at most the reference discloses a list of patient problems and when they were diagnosed:



J.A. 317, Figure 13.

In contrast, the ’067 Application user interface shows *both* pieces of medical encounter information stored in the database in accordance with the claims: the reason for the encounter (the “Complaint” of “dryness of mouth, excessive tiredness”) and the corresponding diagnosis (“Diabetes/Millitus”):



J.A. 125, Fig. 8

There is simply no analogous disclosure in Mayaud. Because the Board erred in finding that Mayaud meets the "storing medical encounter data" limitation in claims 9–18 and claims 23–25, its anticipation decision for those claims should be reversed.

C. The Board Erred in Finding That Mayaud Discloses Patient Compliance Information and Medical Condition Data

The Board also erred in finding that Mayaud discloses the patient compliance and medical condition limitations. First, the Board did not issue sufficient findings for these limitations. That error was particularly acute for the "storing medical condition data" limitation in independent claim 23—the Board *never* addressed that limitation in either decision. Had the Board adequately explained its decision, its findings would have lacked substantial evidence. As a doctor-centric system, Mayaud does not disclose these patient-specific limitations.

1. The Board's Decision Lacks Sufficient Findings and Analysis

The Board's decision does not contain adequate findings and reasoning for the "compliance information" limitations in claims 13, 14, 15, 17, 24, and 25 or the "medical condition data" limitation in claims 23, 24, and 25. "[A] Board opinion must contain sufficient findings and reasoning to permit meaningful appellate scrutiny," and failure to clear this bar is grounds to vacate the Board's decision. *Getcher v. Davidson*, 116 F.3d 1454, 1458 (collecting cases). In *Getcher*, for example, the Court vacated the Board's decision as inadequate because it "lack[ed] a claim construction, ma[de] conclusory findings related to anticipation, and omit[ted] any analysis on several limitations." 116 F.3d at 1460.

The Board's findings here are likewise inadequate. The Board's original decision did not contain *any* findings on the "compliance information" and "medical condition data" limitations, *see* J.A. 6–9, even though Mr. Karpf specifically challenged the examiner's findings on these limitations in his briefing before the Board, J.A. 215–18 (Appeal Brief); J.A. 262–66 (Reply Brief).

The Board attempted to cure its deficient findings on rehearing after Mr. Karpf, proceeding pro se, re-raised the "medical condition data" and "compliance information" limitations in his rehearing request. J.A. 278–79. The Board's findings on rehearing, however, were still inadequate. The Board either ignored Mr. Karpf's arguments or gave them short shrift. The Board first concluded that

the "compliance information" limitation in claim 13 was not a claim limitation. J.A. 16–17. As explained above, that was error. The Board then disposed of the remainder of Mr. Karpf's arguments in a single sentence: "With respect to Appellants' arguments regarding claims 17, 24, and 25, we agree with the Examiner's factual findings regarding these claims and find that the Examiner's findings are supported by a preponderance of the evidence." J.A. 17 (citing J.A. 239–241). The Board's rehearing decision did not mention claims 14, 15, or 23, though Mr. Karpf had separately raised those claims. J.A. 278–79. It also again failed to mention the "storing medical condition data" limitation in independent claim 23.

2. The Lack of Adequate Findings and Analysis Was Prejudicial

The Board's lack of findings and reasoning prejudiced Mr. Karpf. The evidence shows that Mayaud does not disclose the "compliance information" or "medical condition data" limitations. Claims 13, 14, and 17 describe, for example, that the claimed system incorporates a feature of storing compliance information and, in the case of claim 17, displaying that compliance information. Mayaud does not disclose a system that stores whether a patient has complied with a particular treatment regimen. Mayaud is a doctor-focused system—it allows a doctor to

manage the prescriptions for patients. It does not track patient compliance or allow a patient to access the system to view compliance information.

On rehearing, the Board found that the "compliance information" limitations in claims 17, 24, and 25 were met, citing three pages in the examiner's answering brief. J.A. 17 (citing J.A. 239–241). In that section of the answer, the examiner made the following findings:

- Selecting for Display Compliance Information (claim 17): "[T]he user's prescription management system can have built-in, online, statistical reporting functions enabling a physician user to review their, or others, historical experience with a particular drug or condition and providing online historical review of any other activities or data entrusted to the system[.]" (citing J.A. 332, col. 13 ll. 25–30)

- Determining Compliance. . . and Issuing a Notification Based on the Determination of Noncompliance (claim 24): "[R]outine alerts can be passed to administrative personnel associated with the prescribing health care provider, notifying them of any unfilled prescription after a prespecified period of say two weeks or a month, or prescription expiration, or a shorter period for more critical medications[.]" (citing J.A. 326, col. 1 ll. 21–27; J.A. 328, col. 5 ll. 32–43; J.A. 339, col. 28 ll. 38–49).

- Issuing a Notification in the Form of a Reminder Message. . . to Comply With the Medication Regimen Issued (Claim 25): "In the event that a pill or the like is detected in any bay stamped with a date and time prior to the date and time clocked by the device, an audible or visual or remote alert, or a combined alert, is triggered[.]" (citing J.A. 340, col. 30 ll. 16–24).

None of these findings, however, show that the Mayaud system tracks a particular patient's compliance with a treatment regimen or displays that compliance information. At most, the examiner's answer shows that Mayaud

allows physicians to review medications and track whether prescriptions have been filled or not. But that is not determining whether a patient has complied with the doctor's treatment regimen for a particular medical encounter or displaying that compliance information. J.A. 113, claim 17. There is no disclosure in Mayaud of "determining compliance by the given patient with the treatment information . . . for a given medical encounter" and "issuing a notification based on a determination of non-compliance." J.A. 116, claim 24. And there is certainly no disclosure of "issuing a notification in the form of a reminder message" to a patient to comply with the treatment. J.A. 116–17, claim 25.

Mayaud also does not disclose the storing of "medical condition data" recited in independent claim 23. Again, the Board *never* addressed this claim limitation. The limitation requires "storing medical condition data . . . that may be deemed by medical personnel to relate to a patient as a result of a medical encounter, wherein medical condition data includes general information about a given medical condition." J.A. 115–16, clam 23. Mayaud does not disclose any medical condition data that is linked to a particular patient for a given medical encounter. At most, the examiner found that Mayaud discloses that a medical condition is stored. *See* J.A. 250–51. But the claims require more. Thus, Mr. Karpf respectfully requests that, at the very least, the Court should vacate the

Board's decision that Mayaud anticipates claims 13, 14, 15, 17, 23, 24, and 25 and remand this case for further proceedings.

CONCLUSION

For the above reasons, Mr. Karpf respectfully requests that the Court reverse the Board's decision finding claims 9–18 and 23–25 anticipated by Mayaud. At a minimum, the Board's decision should be vacated and remanded.

DATED: January 21, 2014

Respectfully submitted,

_____
Christian J. Hurt

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ADDENDUM

BOARD DECISION

DATED MARCH 18, 2013

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The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte RONALD S. KARPF and
ARTHUR B. WHITE

Appeal 2010-009172
Application 11/645,067
Technology Center 2100

Before MAHSHID D. SAADAT, HUNG H. BUI, and MIRIAM L. QUINN, *Administrative Patent Judges*.

BUI, *Administrative Patent Judge*.

DECISION ON APPEAL

Appellants[1] seek our review under 35 U.S.C. § 134(a) of the Examiner's final rejections of claims 9-18 and 23-25.[2] We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.[3]

---

[1] Real Party in Interest is Ronald S. Karpf & Arthur B. White.
[2] Claims 1-8 and 19-22 have been withdrawn from consideration and are not on appeal.

STATEMENT OF THE CASE

Appellants' Invention

According to Appellants, their invention relates to an electronic medical records (EMR) system including a treatment instructions database for storing electronic medical records and information concerning patients, medical personnel, medical encounters, and other related information. Spec. ¶ [0004]. The EMR system is accessible to: (1) a medical personnel to enter treatment instructions at the time of the examination and (2) a patient to allow the patient to review the patient's records at any time subsequent to the examination. *Id.*, ¶ [0005], and Abstract.

Claims on Appeal

Claims 9 and 23 are the only independent claims on appeal. Claim 9 is representative of the invention, as reproduced below with disputed limitations emphasized:

> 9. A method of using an electronic medical records (EMR) system, the method comprising:
>
> a) forming an EMR database comprising:
> al) for at least ***one patient registered to use*** the EMR system, storing: patient identification data; patient password; and patient personal identification number (PIN);

---

[3] Our decision refers to Appellants' Appeal Brief filed December 10, 2009 ("App. Br."); Reply Brief filed April 8, 2010 ("Reply Br."); Examiner's Answer mailed March 2, 2010 ("Ans."); Final Office Action mailed July 16, 2009 ("FOA."); and the original Specification filed December 26, 2006 ("Spec.").

a2) for at least one medical practitioner registered to use the EMR system, storing: medical personnel identification data; and medical personnel password;

a3) for at least one medical encounter between a patient and medical personnel, storing medical encounter data relating to the at least one medical encounter, wherein the medical encounter data includes information related to the ***at least one reason for the medical encounter***, and ***at least one diagnosis*** by medical personnel corresponding to the medical encounter;

b) allowing access to the EMR database ***through a patient program***, in which ***an authorized patient has access*** only to information related to the authorized patient, wherein the authorized patient is assigned a patient PIN in the EMR database for controlling access to information in the EMR database related to the patient; and

c) allowing access to the EMR database through a medical personnel data entry program, in which authorized medical personnel may access records related to a given patient only upon entry of input data corresponding to the patient PIN assigned to the given patient.

Evidence Considered

The prior art relied upon by the Examiner in rejecting the claims on appeal is:

Mayaud	US 5,845,255	Dec. 1, 1998

Examiner's Rejections

(1) Claims 23-25 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.[4] FOA. 8; App. Br. 7-8.

(2) Claims 9-18 and 23-25 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Ans. 3; App. Br. 8-9.

(3) Claims 9-18 and 23-25 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Mayaud. Ans. 3-10; App. Br. 9-14.

ISSUES

Based on Appellants' arguments, the dispositive issues on appeal are:

(1) Whether the Examiner has erred in rejecting claims 9-18 and 23-25 under 35 U.S.C. § 112, second paragraph, as being indefinite?

(2) Whether the Examiner has erred in rejecting claims 9-18 and 23-25 under 35 U.S.C. § 102(e) as being anticipated by Mayaud?

ANALYSIS

We have reviewed the Examiner's rejections in light of Appellants' arguments that the Examiner has erred. Only those arguments actually made by Appellants in the Appeal Brief have been considered. *See* 37 C.F.R. § 41.37(c)(1)(vii).

[4] The 35 U.S.C. § 112, first paragraph rejection directed to claims 23-25 has been withdrawn as per Examiner's Answer, page 11.

§ 112, Second Paragraph, Rejection of Claims 9-18 and 23-25

Appellants argue that the optional terms "may" and "should" as recited in claims 9, 15, 17 and 23 are not ambiguous and are consistent with the *permissible* use of alternative formats that use terminology such as "OR" and "OPTIONALLY," as discussed in M.P.E.P. §§ 2173.05(h)(II) and (III). App. Br. 8-9. In response thereto, the Examiner asserts that these optional terms render these claims vague and indefinite. Ans. 10. According to the Examiner, if the medical personnel may not access or review, then nothing would happen and none of the steps in the claims would work. *Id.* 10-11.

We disagree with the Examiner. Claims 9, 15, 17 and 23 at issue, *albeit* broad, are not indefinite. The mere fact that performance of the recited steps is dependent on conditions which may not occur does not establish indefiniteness. *See Application of Venezia,* 530 F.2d 956, 189 U.S.P.Q. 149 (C.C.P.A. 1976).

For this reason, we do not sustain the rejection of claims 9-18 and 23-25 under 35 U.S.C. § 112, second paragraph.

§ 102(e) Rejection of Claims 9-18 and 23-25

With respect to independent claim 9, Appellants contend that Mayaud fails to disclose:

> (1) a 'method of using an electronic medical records (EMR) system' in which a *patient* (and not simply a patient's *doctor)* has access to the EMR system" (App. Br. 9; Reply Br. 4-6) (emphasis in original);
>
> (2) "'patient password' that would be required for the *patient* to gain access to its records or the system as a whole ...

> provide no hint that Mayaud 'anticipated' (or even contemplated) allowing a *patient* to access *Mayaud's* prescription system" (App. Br. 10) (emphasis in original); and
>
> (3) specific information about individual "medical encounters" between a patient and medical personnel (e.g., a doctor): "for at least one medical encounter between a patient and medical personnel, storing medical encounter data relating to the at least one medical encounter, wherein the medical encounter data includes information related to the *at least one reason for the medical encounter,* and *at least one diagnosis* by medical personnel corresponding to the medical encounter."

(App. Br. 10-11; Reply Br. 6-7).

However, we are not persuaded by Appellants' arguments. First, and as correctly found by the Examiner, Mayaud discloses an electronic prescription creation system in which a patient's electronic medical record (EMR) is maintained, and in addition to physicians or other health care professionals, the patient can also be granted access to the EMR. Specifically, Mayaud describes:

> Patient record access codes can, in selected instances, be **patient provided**, or **granted** by intelligent security control cards, having been furnished **to the patient** by a system administrator, or agent, prior to the physician encounter. Physician or other user access to a patient's record, or to sensitive details thereof, can thereby be restricted to a need-to-know basis. Access by third parties to physician related data can be similarly protected.

Ans. 3-4; *also see* Mayaud, col. 10, ll. 20-27 (emphasis added). In other words, a patient is also authorized to access his or her EMR, via Mayaud's prescription creation system. As such, and contrary to Appellants' contention, we agree with the Examiner's findings that a patient is

authorized access to Mayaud's prescription creation system. Ans. 12-13; Mayaud, col. 10, ll. 12-15. Second, and in considering Mayaud, it is proper to take into account not only specific teachings of Mayaud, but also the inferences which one skilled in the art would reasonably be expected to draw therefrom. *See In re Preda*, 401 F.2d 825, 826-27 (CCPA 1968). In this regard, once a patient is authorized access to Mayaud's prescription creation system, "patient passwords" or other forms of password protection operating hierarchically at one or more levels are also provided, with varying degrees of access according to the user's level of authorization, as desired. Ans. 14-15; *also see* Mayaud, col. 10, ll. 12-19 and 44-51.

Third, and as correctly found by the Examiner, Mayaud also discloses storing a patient history file and medical record, including diagnostic information to assist physicians or health care providers to make informed decisions regarding a patient. Ans. 15-16; *also see* Mayaud, col. 8, ll. 21-23 and 33-41; col. 14, ll. 40-65. As such, we agree with the Examiner's findings that Mayaud discloses specific type of information (content) about individual "medical encounters" between a patient and medical personnel (e.g., a doctor): "for at least one medical encounter between a patient and medical personnel, storing medical encounter data relating to the at least one medical encounter, wherein the medical encounter data includes information related to the *at least one reason for the medical encounter,* and *at least one diagnosis* by medical personnel corresponding to the medical encounter,"[5] as recited in claim 9.

[5] Even assuming *arguendo* that Mayaud does not disclose specific type of information (content) about patient "medical encounters," which we do not believe, Appellants' arguments are predicated on non-functional descriptive

With respect to independent claim 23, Appellants further contend that Mayaud also fails to disclose: (1) storing of a "patient password" used to grant patient access to data, and (2) specific information about a given "medical encounter" including: "*at least one reason* for the medical encounter, and at least one diagnosis by medical personnel corresponding to the medical encounter." App. Br. 12-14; Reply Br. 9-11 (emphasis in original). However, for reasons discussed *supra*, we do not find Appellants' arguments persuasive.

For the reasons set forth above, we do not find error in the Examiner's position, and, therefore, sustain the Examiner's anticipation rejection of claims 9-18 and 23-25 based on Mayaud.

CONCLUSION

On the record before us, we conclude that the Examiner has erred in rejecting claims 9-18 and 23-25 under 35 U.S.C. § 112, second paragraph, as being indefinite. However, we conclude that the Examiner has not erred in

---

material, *i.e.*, the content of a medical file or a medical record. The *informational content* of non-functional descriptive material is not entitled to weight in the patentability analysis. *See In re Lowry*, 32 F.3d 1579, 1583 (Fed. Cir. 1994) ("Lowry does not claim merely the information content of a memory. . . Nor does he seek to patent the content of information resident in a database."). *See also Ex parte Nehls*, 88 USPQ2d 1883, 1887-90 (BPAI 2008) (precedential); *Ex parte Curry*, 84 USPQ2d 1272 (BPAI 2005) (informative) (Federal Circuit Appeal No. 2006-1003, *aff'd,* Rule 36 (June 12, 2006)); *Ex parte Mathias*, 84 USPQ2d 1276 (BPAI 2005) (informative), *aff'd,* 191 Fed. Appx. 959 (Fed. Cir. 2006). Accordingly, we do not find Appellants' arguments based on the content of the patient medical record to be persuasive.

rejecting claims 9-18 and 23-25 under 35 U.S.C. § 102(e) as being anticipated by Mayaud.

DECISION

As such, we REVERSE the Examiner's final rejections of claims 9-18 and 23-25 under 35 U.S.C. § 112, 2nd paragraph. However, we AFFIRM the Examiner's final rejection of claims 9-18 and 23-25 under 35 U.S.C. § 102(e).

Because we have affirmed at least one ground of rejection with respect to each claim on appeal, the Examiner's decision is affirmed. *See* 37 C.F.R. § 41.50(a)(1).

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv) (2011).

AFFIRMED

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BOARD DECISION ON REHEARING

DATED JUNE 26, 2013

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The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte RONALD S. KARPF and
ARTHUR B. WHITE

Appeal 2010-009172
Application 11/645,067
Technology Center 2100

Before MAHSHID D. SAADAT, HUNG H. BUI, and MIRIAM L. QUINN, *Administrative Patent Judges*.

BUI, *Administrative Patent Judge*.

DECISION ON REQUEST FOR REHEARING

Appellants have filed a Request for Rehearing under 37 C.F.R. § 41.52 for reconsideration of our Decision on Appeal mailed March 18, 2013. In that Decision, we affirmed the Examiner's final rejection of claims 9-18 and 23-25 under 35 U.S.C. § 102(e) as being anticipated by Mayaud (US 5,845,255, Dec. 1, 1998). We have considered the arguments presented by Appellants in the Request for Rehearing, but we are not persuaded that any points were misapprehended or overlooked by the Board in issuing the Decision. As such, the Request for Rehearing is DENIED.

ANALYSIS

37 C.F.R. § 41.52 states in relevant part:

> [t]he request for rehearing must state with particularity the points believed to have been misapprehended or overlooked by the Board. Arguments not raised in the briefs before the Board and evidence not previously relied upon in the brief and any reply brief(s) are not permitted in the request for rehearing except as permitted by paragraphs (a)(2) [i.e., based upon a recent relevant decision of either the Board or a Federal Court] and (a)(3) [i.e., responding to a new ground of rejection made pursuant to § 41.50(b)] of this section.

37 C.F.R. § 41.52(a)(1) (2008).

In this case, Appellants allege that the Board misapprehended the prior art and overlooked numerous Appellants' arguments presented in Appeal Brief and Reply Brief.

First, Appellants allege the Board misapprehended the distinction between Patient Control over data, as disclosed by Mayaud, and Patient Access to data. Req. Reh'g. 2 (emphasis added by Appellants). In particular, Appellants acknowledge that Mayaud discloses, on column 10, lines 20-27(**emphasis** added), that:

> Patient record access codes can, in selected instances, be **patient provided**, or **granted** by intelligent security control cards, having been furnished **to the patient** by a system administrator, or agent, prior to the physician encounter. Physician or other user access to a patient's record, or to sensitive details thereof, can thereby be restricted to a need-to-know basis. Access by third parties to physician related data can be similarly protected.

Nevertheless, Appellants argue that "Patient Record Access Codes," as disclosed by Mayaud, do NOT allow access to the system by the patient, but rather allow a patient to CONTROL which specific physicians or medical personnel can have access to its confidential information on a 'need-to-know' basis. Req. Reh'g. 5-6. According to Appellants, Mayaud's solution is to allow the patient to have control as to which medical professionals (i.e., doctors) should have access to its sensitive medical data; however, the patient is never authorized to use the Mayaud prescription management system. Req. Reh'g. 5-6. Appellants summarize that:

- Mayaud NEVER teaches Patient Access. Mayaud only teaches Patient Control; and
- Mayaud repeatedly teaches that the system is ONLY for the exclusive use of Medical Professionals. Req. Reh'g. 9.

However, the Board has not misapprehended or overlooked this alleged distinction. As explained in our Decision, "we agree with the Examiner's findings that a patient is authorized access to Mayaud's prescription creation system." Ans. 12-13; Mayaud, col. 10, ll. 12-15. In addition to physicians or other health care professionals, a patient can also be granted access to the patient's electronic medical record (EMR). Dec., pp. 6-7.

We also disagree with Appellants' contention that "Patient Record Access Codes" as disclosed by Mayaud (col. 10, ll. 20-27) are strictly limited to Patient Control over data, i.e., only to control which specific physicians or medical personnel can have access to its confidential information on a 'need-to-know' basis, and do not involve Patient Access to data. First, contrary to Appellants' contention, Patient Control necessarily

requires Patient Access to the system prior to creating any types of controls or restrictions for physicians to access the patient's sensitive data. Second, Mayaud further discloses Patient Access. For example, FIG. 16 shows a database management system of Mayaud including a number of user devices 200 and 210 having data access control software and related data files installed therein for access to data by (1) patients, (2) care providers, and (3) organizations. *See* col. 45, ll. 18-25; col. 46, ll. 41-49; and col. 47, ll. 45-46. FIG. 16 is reproduced below:

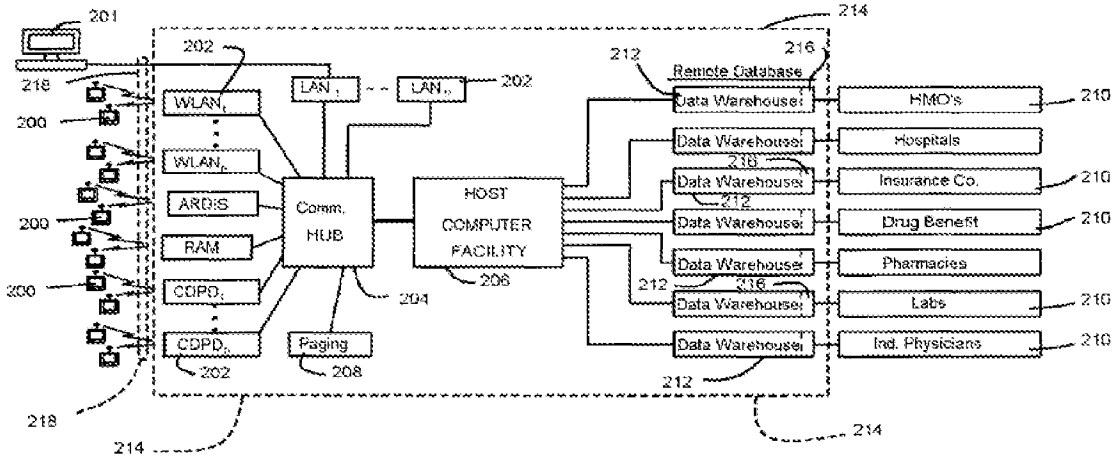

Figure 16

As shown in FIG. 16, the host computer facility 206 provides intelligent network services to user devices 200, 201, and supports ancillary services including patient-directed data access control software to allow a patient at any one of the user devices 200, 201 to access the database system by way of "Patient Record Access Codes" (i.e., patient's data access control card). *See* col. 46, ll. 32-49; and col. 47, ll. 45-46.

Second, Appellants challenge the Board's reliance on *In re Preda*, 401 825, 826-27 (CCPA 1968) and the inferences drawn from Mayaud by one

skilled in the art to utilize "patient passwords" or other forms of password protection. Req. Reh'g 11. In particular, Appellants argue that the Board cannot rely on one skilled in the art to implement complex security and patient confidentiality issues. *Id*. We are not persuaded by Appellants' argument. We reiterate what we stated in our Decision at page 7 that the use of "passwords" or other forms of password protection, which Mayaud discloses as operating hierarchically on one or more levels, supports the Examiner's findings that a user, such as a patient, would be authorized to access Mayaud's prescription system as would be recognized by one skilled in the art. *See* Dec. 7.

Third, Appellants further allege that the Board overlooked numerous Appellants' arguments regarding patentability of dependent claims as presented in Appeal Brief and Reply Brief. Req. Reh'g 12-14. For example, Appellants allege that the Board failed to address dependent claims 13, 14, 17, 24, and 25 as presented on pages 11 and 13 of Appeal Brief and pages 8-11 of Reply Brief. However, the Board has not overlooked these arguments. As explained in our Decision, "we agree with the Examiner's findings that Mayaud discloses specific types of information (content) about individual 'medical encounters' between a patient and doctor" as required by claims 9-18. Dec., p. 7; *also see* Ans. 5-9, 15-23. In addition, we further noted that much of Appellants' arguments are predicated on non-functional descriptive material, i.e., the content of a medical file or a medical record, which is not entitled to weight in the patentability analysis. For example, claims 13 and 14 further define storing compliance information related to at least one diagnosis associated with a given medical encounter, or related to specific treatment instructions issued to a patient and the status of patient compliance

thereto. However, medical data (compliance information) in the database system and communicated on the distributed network does not functionally change the electronic medical records (EMR) system as defined in base claim 9, or alternatively, the machine-readable storage medium as defined in base claim 23. *See In re Lowry*, 32 F.3d 1579, 1583 (Fed. Cir. 1994) ("Lowry does not claim merely the information content of a memory. . . Nor does he seek to patent the content of information resident in a database."). *See also Ex parte Nehls*, 88 USPQ2d 1883, 1887-90 (BPAI 2008) (precedential); *Ex parte Curry*, 84 USPQ2d 1272 (BPAI 2005) (informative) (Federal Circuit Appeal No. 2006-1003, *aff'd,* Rule 36 (June 12, 2006)); *Ex parte Mathias*, 84 USPQ2d 1276 (BPAI 2005) (informative), *aff'd,* 191 Fed. Appx. 959 (Fed. Cir. 2006).

With respect to Appellants' arguments regarding claims 17, 24 and 25, we also agree with the Examiner's factual findings regarding these claims and find that the Examiner's findings are supported by a preponderance of the evidence. *See* Ans. 8-10.

In summary, Appellants have not presented sufficient evidence from Mayaud to support Appellants' interpretation that Mayaud is strictly limited to Patient Control and to persuade us of error in the Examiner's findings. Absent such evidence or persuasive arguments, we do not find error in the Examiner's findings and conclusions, and, therefore, reaffirm the Examiner's anticipation rejection of claims 9-18 and 23-25.

CONCLUSION

We have considered the arguments raised by Appellants in the Request, but find none of these arguments persuasive that our original

Decision was in error. It is our view that Appellants have not identified any points that the Board has misapprehended or overlooked. We have reconsidered our Decision but decline to grant the relief requested. This Decision on Appellants' "Request for Rehearing" is deemed to incorporate our earlier Decision by reference. *See* 37 C.F.R. § 41.52(a)(1).

DECISION

We have granted Appellants' request to the extent that we have reconsidered our Decision, but we deny the request with respect to making any changes therein.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv). *See also* 37 C.F.R. § 41.52(b).

REHEARING DENIED

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CERTIFICATE OF SERVICE

On this 21st day of January, 2014, I electronically filed the foregoing **OPENING BRIEF FOR APPELLANT RONALD S. KARPF** with the Court using the CM/ECF system. The following counsel are registered CM/ECF users and will be served by the appellate CM/ECF system.

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CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B), because it contains 9,283 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii) and Federal Circuit Rule 32(b).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6), because it has been prepared in a proportionally spaced typeface using Microsoft Word 2011 for Mac in Times New Roman 14 point font.

Date: January 21, 2014

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